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For the President of the European Patent Office Le Président de l'Office européen des brevets p.o.

R C van Dijk



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Kit for use in the treatment of lupus and tale and mane eczema

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# KIT FOR USE IN THE TREATMENT OF LUPUS AND TALE AND MANE ECZEMA

The present invention relates to a kit comprising six botanic compositions. The invention further relates to a kit for use in the treatment of disorders in mammals, like humans, horses, cows, pigs and pets, to its use in the treatment of lupus, multiple sclerosis or rheumatoid arthritis in humans or tale and mane eczema in horses and to the use of the kit as a medicament.

Lupus and tale and mane eczema are diseases which are characterized by a complete derangement of the metabolism in a human or horse, respectively. This results in an

- in the skin of homotoxins in the connective tissues located in the skin of humans or in the tale region or mane region of horses. However, it may also manifest itself in other parts of the body, such as internal organs.
- The skin of human patients suffering from lupus is often very sensitive to light. In severe cases direct light exposure should be avoided, ultimately leading to a social isolation of the patient. Further, it is known that patients suffering from lupus may have a poorly working liver or kidney due to progressive attacks of inflammation.
- Horses suffering from tale and mane eczema feel a constant itching in the affected places. To alleviate this itching, horses scratch their affected places on rough surfaces. However, this scratching leads to severe inflammation of the affected places and ultimately the horses are no longer
- 30 capable of functioning normally.

  Although, lupus and tale and mane eczema are diseases which are known for many years, a truly effective cure has not yet

been found. Treatments used at present focus on symptoms, i.e. inflammation, but do not treat the disease itself.

The objective of the present invention is to provide for a medicament which is truly effective for use in the treatment of lupus and tale and mane eczema.

A first aspect of the present invention relates to a kit comprising:

- a first composition comprising leaves of Melissa Officinalis, or parts thereof;
  - a second composition comprising Eleutherococcus senticosus, or parts thereof;
- a third composition comprising Avena sativa, or 15 parts thereof;
  - a fourth composition comprising Ballota Nigra, or parts thereof;
  - a fifth composition comprising roots of Glycyrrhiza glabra/gan cao, or parts thereof; and
- a sixth composition comprising roots of Unicaria Tomentosa, or parts thereof.

It is believed that one of the pharmaceutically active compounds in the leaves of Melissa Officinalis is rose mary acid. It is further believed that the pharmaceutically active compounds of Eleutherococcus senticosus are present in the polyphenol-fraction. Moreover, one of the pharmaceutically active compounds in parts of Bollota Nigra is most likely caffeic acid. Further, it is believed that the pharmaceutically active compounds of the roots of Glycyrrhiza and that the pharmaceutically active compounds of the roots of Glycyrrhiza

30 glabra/gan cao are present in the saponin-fraction and that the pharmaceutically active compounds of the roots Unicaria Tomentosa are present in the alkaloid-fraction.

The above mentioned kit of compositions is especially suited for human patients suffering from lupus and horses suffering from tale and mane eczema, although other mammals may also be treated with it. By administering the compositions of the kit to patients, the system-reticulo-endothelial blockade is lifted and the biofeedback restored. This leads to an improvement of the overall physical condition of the patient. It is believed that due to the improvement of the physical condition of the patient, the homotoxins which are present in connective tissue of the body are broken down. This stops the 10 accumulation of homotoxins in the connective tissue, resulting in a halt to the inflammation of the skin and other organs. Due to the overall improvement of the physical condition of patients, the above mentioned kit can also be beneficial for human patients suffering from other diseases than lupus, such as for example multiple sclerosis or rheumatoid arthritis.

In a prefered embodiment of the kit,

- the first composition comprises a unit dose of 100-1000 mg of leaves of Melissa Officinalis, or parts thereof;
  - the second composition comprises a unit dose of 100-1000 mg of Eleutherococcus senticosus, or parts thereof;
- the third composition comprises a unit dose of 100-1000 mg of Avena sativa, or parts thereof;
  - the fourth composition comprises a unit dose of 100-1000 mg Ballota Nigra, or parts thereof;
- the fifth composition comprises a unit dose of 30 100-1000 mg of the roots of Glycyrrhiza glabra/gan cao, or parts thereof;

- the sixth composition comprises a unit dose of 100-1000 mg of the roots of Unicaria Tomentosa, or parts thereof.
- 5 A second aspect of the present invention relates to a kit comprising:
  - a first composition comprising leaves of Melissa Officinalis, or parts thereof;
  - a second composition comprising Eleutherococcus senticosus, or parts thereof;
  - a third composition comprising Avena sativa, or parts thereof;
  - a fourth composition comprising roots of Piper methysticum, or parts thereof;
- a fifth composition comprising roots of Glycyrrhiza glabra/gan cao, or parts thereof;

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- a sixth composition comprising roots of Unicaria Tomentosa, or parts thereof.
- It is believed that one of the pharmaceutically active compounds in the leaves of Melissa Officinalis is rose mary acid. It is further believed that the pharmaceutically active compounds of Eleutherococcus senticosus are present in the polyphenol-fraction. Moreover, one of the most important pharmaceutically active compounds in the roots of Piper
- 25 methysticum is most likely resine. Further, it is believed that the pharmaceutically active compounds of the roots of Glycyrrhiza glabra/gan cao are present in the saponin-fraction and that the pharmaceutically active compounds of the roots Unicaria Tomentosa are present in the alkaloid—30 fraction.
- The above mentioned kit is especially suited for the treatment of horses, however other mammals may also be

treated with it. It is believed that administering the

compositions of the kit lifts the system-reticulo-endothelial blockade and restores the biofeedback. This leads to an improvement of the overall physical condition of the horse.

Due to the improvement of its physical condition, the

5 homotoxins that cause the itching are broken down. This prevents the homo-toxins from accumulating in the connective tissue of the tale and mane region, resulting in less or no itching.

In a preferred embodiment of the kit of the present

- 10 invention;
  - the first composition comprises a unit dose of 100-1000 mg leaves of Melissa Officinalis, or parts thereof;
  - the second composition comprises a unit dose of 100-1000 mg of Eleutherococcus senticosus, or parts thereof;
- the third composition comprises a unit dose of 100-1000 mg of Avena sativa, or parts thereof;
  - the fourth composition comprises a unit dose of 100-1000 mg roots of Piper methysticum, or parts thereof;
    - the fifth composition comprises a unit dose of
- 20 100-1000 mg roots of Glycyrrhiza glabra/gan cao, or parts thereof.
  - the sixth composition comprises a unit dose of 100-1000 mg roots of Unicaria Tomentosa, or parts thereof.
- In a preferred embodiment of the above mentioned kits, a composition comprises a pharmaceutically acceptable carrier. Moreover, it is preferred if a composition is in the form of a capsule or tablet, although a liquid or sachet may also be used.
- A third aspect of the present invention relates to a kit as described above for use in the treatment of disorders in mammals, like humans, horses, cows, pigs and pets.

A fourth aspect of the present invention relates to a kit as described above for use in the treatment of lupus, multiple sclerosis or rheumatoid arthritis in humans or tale and mane eczema in horses.

5 A last aspect of the present invention relates to the use of a kit as described above as a medicament.

The invention will be described by the following examples.

These examples are given for illustration purposes and are
not intended to limit the scope of the invention.

#### **EXAMPLES**

Example\_1\_

A Spanish female patient suffering from lupus was treated with the compositions of the kit of the present invention. Before treatment the patient had a poor working liver and was very sensitive to light. Exposure to light caused several inflammatory places on the skin. During 5 months the patient was treated with the compositions of the kit of the

- 10 invention. She was administered:
  - three times a day two capsules containing 210 mg of leaves of Melissa Officinalis;
  - three times a day two capsules containing 250 mg of Eleutherococcus senticosus;
- 15 three times a day two capsules containing 250 mg of Avena sativa.
  - three times a day one capsule containing 150 mg of an extract of Ballota nigra;
  - three times a day two capsules containing 250 mg parts of the roots of Glycyrrhiza glabra/gan cao; and
  - three times a day one capsule containing 350 mg parts of roots of Unicaria Tomentosa.

After 6 months the patient was exposed to day-light and no inflammation of the skin took place. Further, MRI-pictures were taken form the liver and they showed that the dark spots, indicating a poorly working liver, had disappeared.

### Example 2

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A group of 102 horses (98 Fjords, 2 Icelanders and 2 Half
30 lings) suffering from tale and mane eczema were treated with
the compositions of the kit of the present invention. Before
treatment the horses had several infections in the tale and

mane region. During a period varying from 1 to 6 months the horses were administered:

- three times a day two capsules containing 210 mg of leaves of Melissa Officinalis;
- 5 three times a day two capsules containing 250 mg of Eleutherococcus senticosus;
  - three times a day two capsules containing 250 mg of Avena sativa;
  - three times a day two capsules containing 300 mg parts of
- 10 the roots of Piper methysticum;
  - three times a day two capsules containing 250 mg parts of the roots of Glycyrrhiza glabra/gan cao;
  - three times a day one capsule containing 350 mg parts of the roots of Unicaria Tomentosa.
- 15 Within a period of six months the conditions of all the horses were evaluated. Seventy nine horses did no longer suffer from tale and mane eczema. Twelve horses showed improvement, although the tale and mane eczema was not cured completely. Eleven horses showed no improvement. It is
- 20 believed that the disease has affect these eleven horses beyond a biological border, making treatment fruitless.

#### CLAIMS

- 1. Kit comprising:
  - a first composition comprising leaves of
- 5 Melissa Officinalis, or parts thereof;
  - a second composition comprising Eleutherococcus senticosus, or parts thereof;
  - a third composition comprising Avena sativa, or parts thereof;
- a fourth composition comprising Ballota Nigra, or parts thereof;
  - a fifth composition comprising roots of Glycyrrhiza glabra/gan cao, or parts thereof; and
    - a sixth composition comprising roots of
- 15 Unicaria Tomentosa, or parts thereof.
  - 2. Kit according to claim 1, wherein
  - the first composition comprises a unit dose of 100-1000 mg of leaves of Melissa Officinalis, or parts thereof;
- the second composition comprises a unit dose of 100-1000 mg of Eleutherococcus senticosus, or parts thereof;
  - the third composition comprises a unit dose of 100-1000 mg of Avena sativa, or parts thereof;
- the fourth composition comprises a unit dose of 25 100-1000 mg Ballota Nigra, or parts thereof;
  - the fifth composition comprises a unit dose of 100-1000 mg of the roots of Glycyrrhiza glabra/gan cao, or parts thereof;
- the sixth composition comprises a unit dose of 30 100-1000 mg of the roots of Unicaria Tomentosa, or parts thereof.
  - 3. Kit comprising:

- a first composition comprising leaves of Melissa Officinalis, or parts thereof;
- a second composition comprising Eleutherococcus senticosus, or parts thereof;
- a third composition comprising Avena sativa, or parts thereof;
  - a fourth composition comprising roots of Piper methysticum, or parts thereof;
    - a fifth composition comprising roots of
- 10 Glycyrrhiza glabra/gan cao, or parts thereof;
  - a sixth composition comprising roots of Unicaria Tomentosa, or parts thereof.
    - 4. Kit according to claim 3, wherein
      - the first composition comprises a unit dose of
- 15 100-1000 mg leaves of Melissa Officinalis, or parts thereof;
  - the second composition comprises a unit dose of
  - 100-1000 mg of Eleutherococcus senticosus, or parts thereof;
  - the third composition comprises a unit dose of 100-1000 mg of Avena sativa, or parts thereof;
- the fourth composition comprises a unit dose of 100-1000 mg roots of Piper methysticum, or parts thereof;
  - the fifth composition comprises a unit dose of 100-1000 mg roots of Glycyrrhiza glabra/gan cao, or parts thereof.
- the sixth composition comprises a unit dose of 100-1000 mg roots of Unicaria Tomentosa, or parts thereof.
  - 5. Kit according to any of the claims 1-4, wherein a composition comprises a pharmaceutically acceptable carrier.
- 6. Kit according to claim 1-5 wherein a composition 30 is in the form of a capsule or tablet.
  - 7. Kit according to any of the claims 1-6 for use in the treatment of disorders in mammals, like humans, horses, cows, pigs and pets.

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- 8. Kit according to any of the claims 1-6 for use in the treatment of lupus, multiple sclerosis or rheumatoid arthritis in humans or tale and mane eczema in horses.
  - 9. Use of a kit according to claim 1-6 as a
- 5 medicament.

#### ABSTRACT

The invention relates to a kit comprising:

- a first composition comprising leaves of Melissa Officinalis, or parts thereof;
  - a second composition comprising Eleutherococcus senticosus, or parts thereof;
- a third composition comprising Avena sativa, or
- 10 parts thereof;
  - a fourth composition comprising Ballota Nigra, or parts thereof;
  - a fifth composition comprising the roots of Glycyrrhiza glabra/gan cao, or parts thereof; and
- Unicaria Tomentosa, or parts thereof. To the kit for use in the treatment of disorders in mammals, like humans, horses, cows, pigs and pets. To the kit for use in the treatment of lupus, multiple sclerosis or rheumatoid arthritis in humans
- 20 or tale and mane eczema in horses, and to its use as a medicament.